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| 10/670,118 | 09/24/2003 | Salim Yusuf | 16554-002002 / H310864USC | 2545 |
| 69713 7590 08/02/2007 OCCHIUTI ROHLICEK & TSAO, LLP 10 FAWCETT STREET CAMBRIDGE, MA 02138 | | | EXAMINER NGUYEN, BAO THUY L | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,118

Applicant(s)

YUSUF ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment dated 02 May 2007 has been received.
2. Claims 1-10 have been withdrawn.
3. Claim 11 has been canceled.
4. Claims 12-15 have been added and are under consideration.
5. All rejections not reiterated herein below are withdrawn in view of the cancellation of claim 11.

Priority

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. PCT/CA03/00422 and US 60/367,883, fails to provide adequate support or enablement in the manner

provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Claim 12 is directed toward a device comprising a first strip having a plurality of standard patches, each having a predetermined amount of labeled anti-thromboxane antibody, and a test patch comprising a predetermined amount of labeled antibody specific to thromboxane B2; and a second strip comprising an absorbent material.

'883 and '422 both disclose an embodiment where the first strip (1) has a fixed concentration labeled antibody specific for thromboxane B2 and the second strip (7) is made of a material designed to absorb a fixed volume of liquid sample. The first strip may also have protein A or G to facilitate the attachment of the labeled antibody to the strip. Nowhere in these two documents can support be found for the immunoassay system of claim 12.

Therefore, this application is only entitled to the instant filing date of 24 September 2003.

Applicant asserts that claim 12 is supported at pages 5 and 6 of US 60/367,883; however, a review of these pages as well as the entire application does not reveal adequate support for the claimed invention.

Page 6 of 60/367,883 teaches a device comprising two strips, strip 1 having labeled antibody to thromboxane B2 and strip 7 is configured to receive a urine sample. The patches 3, 4, 5 and 6 on strip 1 have reference marks that allow comparison between

the level of florescence resulting from the reaction and the visual amount that would correspond to different level of thromboxane B2.

Nowhere in the 60/367,883 specification is there a disclosure of a device comprising a strip having a plurality of standard patches having a *predetermined amount of labeled anti-thromboxane antibody* AND a test patch comprising a predetermined amount of labeled antibody to thromboxane B2. The *reference marks* disclosed by '883 do not provide adequate support for *standard patches having a predetermined amount of labeled anti-thromboxane antibody*.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-15, "An immunoassay" should be changed to -The immunoassay – for clarity.

Claim 13, the recitation of "thromboxane B2 in the sample bound to the second strip" is vague. It is unclear what is meant by this recitation. Is the thromboxane B2 in the sample or is it fixed to the second strip?

Claim 15, what is "quartiles?"

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire et al (US 4,826,759) in view of Reinke et al (IDS - AT).

The instant claim is drawn to an immunoassay system comprising a first strip having a plurality of patches, each having a predetermined amount of labeled anti-

thromboxane antibody specific for thromboxane B2, and a second strip of absorbent material. The recitation of intended use is not given patentable weight.

Guire discloses an apparatus in the form of a strip comprising a support means provided with a groove intermediate its ends forming a crease line upon which the strip can be folded upon itself. The strip comprising bibulous elements made of filter paper. Guire teaches that the device is suitable for a variety of analytes and makes use of ligand-receptor pairs and labeled pair member as detection. See column 1, line 52 through column 2, line 30. Guire specifically teaches an embodiment where different, predetermined amount of enzyme-labeled analyte is impregnated in one bibulous element and anti-analyte antibody is loaded in another bibulous element. In use, sample is added to the first element and the device is folded to bring the two elements into contact. The contacting elements are pinched together momentarily to transfer liquid from one element to the other element, following which the apparatus is opened and the elements are observed for the development of color. See column 7, lines 58 through column 8, line 57 and claim 5.

Guire differs from the instant invention in failing to teach that the apparatus contains antibody specific for thromboxane B2 and standard concentration of labeled-thromboxane B2.

Reinke, however, discloses the importance of detecting thromboxane B2 and teaches assays for their detection. Reinke discloses thromboxane B2-BSA conjugates,

monoclonal antibodies specific to thromboxane B2 and three different types of enzymes detection system.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Guire to detect thromboxane B2 using the reagents taught by Reinke because Guire teaches that their device is suitable for a variety of analytes with the choice of appropriate reagents. A skilled artisan would have had a reasonable expectation of success in using the device taught by Guire to detect thromboxane B2 because Reinke teaches that the measurement of thromboxane is important because an increase in biosynthesis of thromboxane is observed in patients with coronary diseases as well as a hosts of other problems, and Guire teaches that their device is unique in that it can be readily and easily used or performed by minimally trained personnel.

Response to Arguments

9. Applicant's arguments filed 02 May 2007 have been fully considered but they are not persuasive.

Applicant argues that Guire does not disclose a group of standard patches for quantifying thromboxane B2 in a sample. Applicant also argues that the instant device comprises standard patches such that the signal released from which indicates an amount *range* of the analyte, and by comparing the strength of the signal yielded from

each test patch, an approximate quantity of the analyte in the sample can be determined.

This argument is not persuasive. As indicated above, the instant claim 12, for example, is drawn to a device where a first strip having a plurality of patches, including the so-called "test patch", each patch having a predetermined amount of labeled antibody such that a signal released from the patch is indicative of an amount of the analyte that is in the sample. Guire discloses exactly this. The patches of the instant device is not recited as having different amounts of labeled antibody nor does claim 12 recites the ability of the device to detect an amount *range* of the analyte in a sample. The fact that the different patches of the instant device is designated as "standard patches" and "test patch" does not alter its properties. Mainly, the patches contain predetermined amount of labeled antibody, which is taught by Guire.

Guire does differ from the instant claim in failing to teach the detection of thromboxane B2. However, Guire does teach that their device is suitable for a variety of analytes with the choice of appropriate reagents. And Reinke discloses the importance of detecting thromboxane B2 and teaches assays for their detection. Reinke discloses thromboxane B2-BSA conjugates, monoclonal antibodies specific to thromboxane B2 and three different types of enzymes detection system.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Guire to detect thromboxane B2 using the reagents taught by Reinke. A skilled artisan would have had

a reasonable expectation of success in using the device taught by Guire to detect thromboxane B2 because Reinke teaches that the measurement of thromboxane is important because an increase in biosynthesis of thromboxane is observed in patients with coronary diseases as well as a hosts of other problems, and Guire teaches that their device is unique in that it can be readily and easily used or performed by minimally trained personnel.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571)

272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

7/21/07